UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,444	05/22/2002	Christian Von Falkenhausen	3868-0113 P	6939

2292 7590 11/20/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,444	FALKENHAUSEN ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Response dated 8/17/06.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of the Griffin et al (EP 0 010 987 hereafter '987) and Biegajski et al (USPN 5,700,478 hereafter '478). The claims are drawn to a controlled release preparation where the active agent is disposed onto a laminated sheet, and the sheet is rolled or folded.

2. The '987 reference discloses a rolled up preparation for the controlled release of active agent in the body (abstract). The laminate comprises an erodible layer, which contains the active agent, and a non-erodible layer (Figure 1). When the preparation is rolled the diameter greater than 0.5 mm (page 8, line 10-30). The device can be covered with equally erodible layers for delivery (page 6, line 28-34). The device is designs to open and assume a flat shape once in the

stomach (abstract). The particular release profiles can be determined though routine experimentation and changed to fit the needs of the patient (page 5, line 1-14). The drug-containing layer is attached to a carrier, rolled, and delivered to the patient (examples). The device can further comprising water-soluble layers that help unfold the device (page 8, line 1-9). The reference is silent to the inclusion of a pressure-sensitive adhesive layer, though it is disclosed that some polymers in the laminate may be sticky and a water-soluble polymer such as rice paper or other water-soluble polymers should be used (page 8, line 1-9). The inclusion of a pressure-sensitive adhesive however would be obvious to an artisan of ordinary skill since they would want the unfolded patch to adhere to the delivering surface. These pressure sensitive adhesive polymers would be readily available and obvious to one of ordinary skill as seen in the '478 patent.

3. The '478 patent discloses a water-soluble pressure-sensitive adhesive that may constitute a part of a device that must be held at a particle point in the body (abstract). The adhesives are particularly useful in the construction of laminated devices for the controlled delivery of substances within a mucosa-lined environment such as mouth, rectum and vagina (col. 3, lin. 45-50). The release can be controlled by the structure of the device and can fit various dosing regimens (col. 4, lin. 1-20). The adhesive layers can dissolve once exposed to body fluids adding to the delivery options (col. 4, lin. 21-46). The layers must be cut and shaped in order to fit the contours of the mouth (col. 10, lin. 30-35). The layers adhere to the surface that they are applied to and dissolve away upon exposure to body fluids (col. 10, lin. 1-14). Though not expressly stated it can be assumed that since not every mouth is the same and the contours of a mouth are not geometrically square, the films of the '478 patent would be non-uniform in at least one

direction. It would have been obvious to include the pressure sensitive adhesive layers of the '478 into the rolled device of the '987 in order to insure a preferred release and adherence to the specific application situs. Further the layers of the '478 patent would be useful in providing an improved fit in the body cavity since they are shaped to fit the application situs.

4. The references are silent to the inclusion of active agents in the water-insoluble layer. However, it is the position of the examiner that such a limitation lacks criticality barring a showing thereof. The device of the reference performs identically to that of the instant claims, and is within the same field of endeavor. Further the orientation of the drug-containing sheet can be determined by routine experimentation and by those of ordinary skill in the art. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

5. With these aspects in mind it would have been obvious to include the pressure sensitive adhesives of the '478 patent into the carriers of the rolled device of the '987 in order to provide a specific differential release of active agents and allow the device to adhere to the body internally insuring proper release of the active agents. It would have been obvious to combine the

teachings and suggestions of the art with an expected result of an adhesive patch capable of variable release rates.

Response to Arguments

6. Applicant's arguments filed 8/17/06 have been fully considered but they are not persuasive. Applicant argues that:

a. The Griffin reference does not disclose a non uniform controlled release layer

b. The Griffin reference teaches away from the inclusion of adhesives.

c. The Biegajski reference does not cure these deficiencies.

d. There is no motivation to combine the two references since Griffin is silent to oral mucosal adhesion and Biegajski only deals with oral adhesion.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Griffin reference is relied upon for its disclosure of an implanted roll-up device that unrolls upon delivery and delivers active agents through two separate layers. The reference was not relied upon for a disclosure of a non-uniform layer. If so the reference would be anticipatory, as such the Biegajski reference is relied upon. The Biegajski reference provides a pressure sensitive adhesive layer that dissolves in body fluids. It is the position of the Examiner that the artisan of ordinary skill would be motivated to include the adhesives of the '478 patent in order to improve the fit of the dosage form and the delivery of the active agents.

8. Regarding argument b., the Examiner disagrees with Applicant's assessment of the Griffin reference teaches away from tacky or adhesive polymers. The Griffin reference states that certain polymers can be tacky and when they are sued, water soluble coats are need to completely unfold the sheet. However it is never stated that a quick unrolling is required or that anything must be done so that the device quickly unfolds. The layer should be added in the Griffin patent to ensure **full** unfolding, whenever that occurs. The Griffin reference does not teach against adhesiveness, but merely away from incomplete unfolding.

9. As discussed above the Biegajski reference is relied upon for its adhesive layers that can be applied to any mucosal surface. The devices are used to deliver agents while adhering to a mucosal surface and can be delivered anywhere in the body. They comprise similar polymers to the patches of the Griffin reference. A skilled artisan would be motivated to include the patches since they have similar polymers and deliver similar agents to the body. The patches of the secondary reference are cut and shaped to fit their respective delivery site, meaning they would have an irregular shape. Also Griffin suggests that the patches are shaped to best fit the delivery site. For these reasons at least the combination of prior art obviates the claims.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., timed delivery, slow unfolding, a specific release profile) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant that the adhesive causes the slow unfolding, however it is the position of the

Examiner that the adhesives of the Biegajski reference would operate identically since all that is required of the invention is an adhesive.

11. In conclusion, the Griffin reference provides a rolled laminate comprising a water-soluble and non-soluble layer. The layer can comprise adhesive polymers, though a separate layer must be added to ensure full release. The laminates are cut to better fit the application site and to ease administration. The Griffin reference is silent to specific adhesives and specific non-uniform structures. The Biegajski provides adhesive pressure sensitive layers that are administered to mucosally lines body cavities. The pressure sensitive adhesives must be cut and shaped to form fit the specific application site. Since individuals are different and the adhesives are meant to remain in place the shoes of the adhesives differ in dimension. The layers would be added to the Griffin invention in order to improve the adhesion and placement of the unrolled drug delivery device.

12. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

13. For these reasons at least the claims remain obviated by the teachings and suggestions of the art.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER